EXHIBIT 9
DATE 3.11.15
HB 479

To: Chairman Wittich and members of the House Human Services Committee
From: Thomas C. Key, M.D.
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Please vote NO on HB479

I am concerned regarding the upcoming House Bill 479 entitled 'Montana Unborn Child Pain and Suffering Prevention Act.'

Firstly, this is a wide ranging attempt to seek a ban on abortion which could well be extended to any age, given the very poorly constructed and defined scope of this particular proposal. To use a guise of fetal pain as a reason to restrict an abortion for reasons of choice or for medical reasons involving the mother or child's health is not supported by mainstream science and/or medical therapies. The use of fetal analgesia/anesthesia for fetal surgery per se should not be confused with the intent of this bill. I find the bill poorly written, very vague in its intent and without medical foundation. Furthermore, the bill does not provide direction to the physician or patient exactly how "fetal anesthesia' to be accomplished.

In general the decision to terminate a pregnancy after 20 weeks' gestation is usually for grievous maternal illness and/or life threatening or altering fetal disease. In my mind, there are three basic scientific considerations that this bill either does not address or truncates; (1) the mis-statement of scientific fact regarding the fetus and the perception of pain, (2) the procedures necessary to deliver anesthesia/analgesia to the unborn with attendant risks to the mother, (3) an absolute absence of data establishing any defined/proved benefit for the unborn fetus and/or its mother.

Evidence regarding the capacity for fetal pain is limited but indicates that fetal perception of pain is unlikely before the third trimester. Little or no evidence addresses the effectiveness of direct fetal anesthetic or analgesic techniques. Similarly, limited or no data exist on the safety of such techniques for pregnant women in the context of abortion. Anesthetic techniques currently used during fetal surgery are not directly applicable to abortion procedures.

Pain perception requires conscious recognition or awareness of a noxious stimulus. Neither withdrawal reflexes nor hormonal stress responses to invasive procedures prove the existence of fetal pain, because they can be elicited by nonpainful stimuli and occur without conscious cortical processing. Fetal awareness of noxious stimuli requires functional thalamocortical connections. Thalamocortical fibers begin appearing between 23 to 30 weeks' gestational age, while electroencephalography suggests the capacity for functional pain perception in preterm neonates probably does not exist before 29 or 30 weeks. For fetal surgery, women may receive general anesthesia and/or analgesics intended for placental transfer, and parenteral opioids may be administered to the fetus under direct or sonographic visualization. In these circumstances, administration of anesthesia and analgesia serves purposes unrelated to reduction of fetal pain, including inhibition of fetal movement, prevention of fetal hormonal stress responses, and induction of uterine atony.

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Anesthetics and analgesics are commonly used to alleviate pain and discomfort. Despite ongoing debate regarding fetal capacity for pain, fetal anesthesia and analgesia are still warranted for surgical procedures undertaken to promote fetal health. When long-term fetal well-being is a central consideration, evidence of fetal pain is unnecessary to justify fetal anesthesia and analgesia because they serve *other* purposes unrelated to pain reduction, including (1) inhibiting fetal movement during a procedure; (2) achieving uterine atony to improve surgical access to the fetus and to prevent contractions and placental separation; (3) preventing hormonal stress responses associated with poor surgical outcomes in neonates; and (4) preventing possible adverse effects on long-term neurodevelopment and behavioral responses to pain.

These objectives are not applicable to abortions. Instead, beneficence toward the fetus represents the chief justification for using fetal anesthesia or analgesia during abortion—to relieve suffering, if fetal pain exists. **As with any clinical decision, thorough safety and risk-benefit analyses should be undertaken before performing an intervention. Because the principle of beneficence also requires the woman's physician to act in her best interests, *potential* fetal benefit must be weighed against *real* risks to the woman's health.** The safety and effectiveness of proposed fetal anesthesia and analgesia techniques are discussed below.

Fetal surgery involving laparotomy, hysterotomy, or both requires general or regional anesthesia. Regional anesthesia, such as epidural anesthesia, does not anesthetize the fetus. General anesthesia is more commonly used because it induces uterine atony and fetal immobilization. Studies of inhalational agents in pregnant ewes determined that a dose capable of anesthetizing the ewe also anesthetized the fetus. Administering fentanyl, pancuronium, or vecuronium to the fetus intramuscularly may supplement analgesia or immobilization. For pregnant women, general anesthesia is associated with increased morbidity and mortality, particularly because of airway-related complications and increased risk of hemorrhage from uterine atony. Historically, general anesthesia was used in abortions, even in the first trimester, until studies found that general anesthesia was a leading cause of abortion-related mortality. In addition to safety concerns, general anesthesia increases the cost of abortion, making it prohibitively expensive for the majority of patients who pay out of pocket.

In contrast to fetal surgery requiring regional or general anesthesia, minimally invasive fetal procedures do not involve maternal laparotomy or hysterotomy and instead use needles or endoscopy to access the fetus. For the sake of reducing pain, the increased risks of general anesthesia are unjustified for these procedures; adults typically undergo similar procedures with no analgesia or only local analgesia. No established fetal analgesia protocol exists for these procedures, although 3 techniques have been proposed, namely, direct delivery of medications to the fetus, delivery of medications to the fetus via maternal intravenous infusion, and intra-amniotic delivery of medications.

Direct Delivery. One group has examined the effects of analgesics delivered directly to human fetuses during minimally invasive procedures. Twenty-eight fetuses that received intravenous fentanyl before hepatic vein blood transfusions had diminished changes in plasma β-endorphin concentration and cerebral blood flow, compared with fetuses not receiving fentanyl. The cortisol response was not significantly decreased with fentanyl. The investigators did not

examine risks for the woman, such as infection or uncontrolled bleeding. Furthermore, reducing the stress response is distinct from reducing pain. For example, plasma glucose and cortisol concentrations may not differ significantly between adults with and without postoperative pain.

Delivery via Maternal Intravenous Infusion. To achieve presumably effective fetal plasma concentrations of fentanyl by placental transfer, potentially unsafe doses would need to be administered to the woman. Although standard doses of fentanyl are generally safe for maternal analgesia during labor, *fentanyl can pose serious risks such as hypoventilation if maternal doses are significantly increased to achieve more extensive placental transfer.* Severe maternal hypoventilation may require endotracheal intubation, which increases risks and costs for the woman, as described above.

No data exist on the dosing or efficacy of using medications such as diazepam and morphine for fetal analgesia via maternal intravenous infusion, although studies have characterized the placental transfer of these medications. Two related studies found that low-dose remifentanil via maternal intravenous infusion achieved fetal immobilization during laser coagulation of placental vessels. However, immobilization is not the equivalent of pain reduction, and these procedures did not involve surgery on the fetus.

Intra-amniotic Delivery. Intra-amniotic injection would be technically simpler than direct fetal injection, although the drug must be absorbed through fetal membranes and skin. Intra-amniotic sufentanil injection in 10 pregnant ewes resulted in fetal plasma concentrations that would control postoperative pain in human adults. Sufentanil concentrations in the ewes also reached adult human therapeutic concentrations without causing significant hemodynamic changes. However, the study did not evaluate fetal response to noxious stimuli, and no data exist regarding safety or effectiveness in humans.

Thus in summary, this bill puts forward a theory masquerading under a banner of beneficence while targeting not the beneficence of the requirement but rather abortion itself - placing an unusual burden on physicians and those patients who have very unfortunate reasons for seeking termination. **Ill-defined, ill-presented and poorly written wherein the true intent has little to do with a true and rational understanding of the fetus and its ability or inability to perceive pain.** I see this as a yet another attempt to hinder a woman's access to Choice, at all gestational ages.

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Much of the information in this testimony is from the following article in the Journal of the American Medical Association:

Susan J. Lee, JD, Henry J. Peter Ralston, MD, and Eleanor A. Drey, MD. "Fetal Pain: A Systematic Multidisciplinary Review of the Evidence." *The Journal of the American Medical Association* 294.8 (2005): n. pag. Web. 10 Mar. 2015. <http://jama.jamanetwork.com/article.aspx?articleid=201429>.

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